INNOVATION DIALOGUES

Catalogue of challenges and opportunities identified in the scope of innovation dialogue

Kazimierz Murzyn
Klaster LifeScience Krakow

Anna Eckers
Life Science Nord Management GmbH

EUROPEAN UNION
EUROPEAN REGIONAL DEVELOPMENT FUND

Interreg Baltic Sea Region

BFCC
Baltic Fracture Competence Centre

- Life Science Nord Management GmbH (Germany)
- Stryker Trauma GmbH (Germany)
- University Medical Center Schleswig-Holstein (Germany)
- University Medicine Greifswald (Germany)
- Sahlgrenska University Hospital (Sweden)
- ScanBalt fmba (Denmark)
- Lithuania University of Health Sciences (Lithuania)
- LifeScience Krakow Klaster (Poland)
- University Hospital in Krakow (Poland)
- University of Tartu (Estonia)
- Tartu Biotechnology Park (Estonia)
- Bone Index Finland Ltd. (Finland)
- BONESUPPORT AB (Sweden)

Catalogue of challenges and opportunities
Kazimierz Murzyn, Klaster LifeScience Krakow
Anna Eckers, Life Science Nord Management GmbH

Design concept
amt tipografia design gráfico
Anne Mayer-Tasch
Friedrichsdorf, Germany
https://amt.myportfolio.com/

Photos & illustrations
Shutterstock.com:
Spotmatik Ltd (p. 4)
Adobe Stock:
Wladimir1804 (p. 5), stokkete (p. 14), jenshagen (p. 26), Ideeah Studio (p. 29), maxism (p. 31)
All unmarked illustrations:
Anne Mayer-Tasch

Published in April 2019

Lead partner & publisher
Baltic Fracture Competence Centre
Life Science Nord Management GmbH
Legienstraße 40, 24103 Kiel, Germany
+49 431 90 89 68 58
Contact: Imke Schneemann
schneemann@lifesciencenord.de
www.lifesciencenord.de

www.bfcc-project.eu

Supported by:

Interreg Baltic Sea Region
EUROPEAN UNION
EUROPEAN REGIONAL DEVELOPMENT FUND

CONTENTS

BFCC—BALTIC FRACTURE COMPETENCE CENTRE

The Baltic Fracture Competence Centre (BFCC) is a pan-Baltic fracture cooperation network fostering innovation within fracture management. The project consortium consists of a transnational cross-sector partnership involving five hospitals, three companies from the medical technology industry, a university, three clusters and one technology transfer organization.

Due to an ageing society, the need for innovative products and clinical procedures for fracture treatment is increasing as a response to age-related fractures and co-morbidities such as osteoporosis, infections and non-unions. Innovations in fracture management must reduce the cost of care or clearly improve quality of care.

Clinicians will support the innovation process by identifying the clinical needs to ensure user-oriented product development. The collaboration between hospitals across countries will foster the innovation of clinical procedures through the exchange of best practice in fracture management influenced by different national, organizational and regulatory conditions.

However, clinicians and companies often lack insight information about total cost and effectiveness of fracture management and causes of adverse health outcomes in the hospitals. To overcome this information gap, the BFCC will develop and implement a transnational fracture registry with five hospitals from Estonia, Germany, Lithuania, Poland, and Sweden, respectively, providing evidence about fracture treatment in the clinical »real world« and reveal clinical needs as well as potentials for innovation.

The BFCC will publish two innovation reports. The Innovation Report No 1 deals with trends in the surgical treatment methods of proximal femur fractures. The Innovation Report No 2 based on results and findings from registry data analysis will identify innovation needs and potentials.

PHOTO: Shutterstock

1. INTRODUCTION

Establishing a dialogue between clinicians to continuously identify and assess clinical best practice and needs for innovation in fracture management, as well as translating these findings into further hospitals and companies in the BSR was one of the main demands within the BFCC network. Discussions by partnering hospitals were taken further in innovation dialogue events targeted at clinicians, health professionals and industry.

This output aims at documenting both, the analysis of innovation needs and clinical best practice and innovation gaps derived from clinical dialogue (GoA4.1) resulting in recommendations in chapter 4, and the outcomes of the innovation dialogue events (GoA4.2) as described in chapter 3.

In contrast to the originally planned procedure of first having the clinical dialogue, then running the innovation dialogue with industry, having a transnational forum meeting and a second set of innovation dialogue afterwards, the process was adapted during the project's runtime as by combining those a better feasibility and more desirable results could be achieved. That way, an evaluation of the outcomes of the local meetings, exchange on using the dialogue methodology (see chapter 2.2) as well as the optimisation of organisational, dialogue and follow-up processes were done continuously instead of a one-step-after-the-other procedure. An intensive dialogue was held by the project partners and the involved stakeholders from clinic and industry: Comprehensive discussions about the patients' and clinical needs to improve fracture management, providing an insight understanding of the problems and challenges for industry, inspiring companies to adopt their business strategies and R&I investment to better meet the needs of daily fracture treatment.

Recommendations, possibilities and starting points for future innovation within the field of fracture management are the main content outlined in this documentation. With these information, health actors in the BSR have the opportunity to align their innovation activities with existing clinical needs. This compilation is part of the BFCC innovation library.

PHOTO: Adobe Stock

2. THE SCOPE OF THE REPORT

According to the project proposal, the aim of WP4 was to establish a dialogue between stakeholders (mainly clinicians and business innovators) with the view for continuous identification and assessment of clinical best practice and needs for innovation in fracture management. The objective was to build a high level of involvement of clinicians, health professionals and industry representatives outside the project consortium in the dialogue and the (planned) innovation initiatives deriving from the transnational dialogue. The resulted report aims to translate the findings to further hospitals and companies in the BSR.

These findings involve the innovative and successful treatment methods and overall handling of patients identified in the dialogue or through the analysis of registry data, and are disseminated via the network of stakeholders identified in the BSR. In addition, it was assumed that findings will be translated for the clinical improvement of fracture management through targeted education and training measures for clinicians and health professionals.

To that end, the report includes outcomes from:

a) **Analysis of Innovation Needs and Clinical Best Practice.** The key stakeholders giving input to the results were clinicians and health professionals. The aim was to engage with these group members in comprehensive discussions about the patients' and clinical needs to improve fracture management. The transnational approach allows to increase significantly the variety of perspectives and ideas for innovation needs. The hospitals from the project consortium engaged in discussions regarding experiences in fracture management and best practices and clinical needs for innovation.

b) **Innovation Dialogue from a Clinical Perspective.** The key players involved were representatives of the business sector. The approach was to discuss the innovation needs and potentials identified by clinicians with industry representatives which should get an insight understanding of the problems and challenges which clinicians and health professionals face in their daily work. This knowledge is especially valuable for SMEs which are usually confronted with the challenge in establishing and maintaining a network with hospitals and clinicians across borders. Companies get inspiration to adopt their business strategies and R&I investment to better meet the clinical need in fracture management.

The results of WP4 activities were presented and discussed during the **BFCC Transnational Forum Meeting** held in Krakow in October 2018 in combination with the Life Science Open Space. The main objective of the forum was to exchange findings and experiences from analysis and dialogue meetings as well as to present the information to the industry representatives from the BSR and to demonstrate and discuss innovation gaps and potentials.

Recommendations, possibilities and starting points for future innovation within the field of fracture management are the main outcomes included in the innovation dialogue reports as results from activities performed in participating hospitals.

In addition, the report involves a summary of the coherent methodology aimed to guide the innovation dialogue meetings in a way to deliver valuable and comparable results.

2.1. Purpose and target groups

The purpose of this report is to supply all stakeholders from the BSR with the new knowledge regarding the innovation needs of hospitals, clinicians and health professionals within fracture management gained during the BFCCs activities stated above. It is expected that businesses will use this knowledge to adopt their business and research and innovation (R&I) strategies.

The objective is to change behaviour of clinicians and hospitals which should adopt their clinical procedures in fracture management and their willingness to invest in new medical technology or pharmaceutical products to improve the clinical outcome and cost-effectiveness.

The innovation needs have been identified in the scope of eight innovation dialogue meetings (IDM) performed in hospitals participating in the BFCC project. Participants of these innovation meetings were given a task to rethink and restructure their own observations based on experiences and help to redefine observations of others with the view to turning this observations into the opportunities and challenges. It was also expected that the process would change or sharpen their perception of the problem as well as it would influence their approach and support positive attitude for further cooperation. The innovation dialogue reports (IDR) collected as the deliverables of locally executed IDMs are published on the project website as well as made available to the interested parties.

2.2. The innovation dialogue meetings

The objective of the IDM was to identify innovation needs and potentials as well as best practices. It was aimed that each IDM will deliver:

a) Structured description of two challenges / opportunities identified during the meeting.
b) Description of the best practices in use identified in conjunction to identified challenges.
c) Background information – notes and issues identified during a discussion taken to provide a whole picture of the process and to enable detailed investigation of a source data.
d) Contact data of participants of the meeting to allow direct contact for in depth investigation of the issue.

The innovation dialogues did not aim to provide answers nor ideate the solution to the identified issues and problems, which is the aim of the next phase in the innovation process, i.e. “innovation development”. To that end, the aim of the IDM was to build a bridge between clinic and industry, to exchange knowledge and thus to prepare the development of innovation.

The Method

In order to prepare the IDR, the practical approach has been proposed to combine elements of two well-known methods, i.e. “design thinking” and “blue ocean strategy”. The process aimed to focus on a definition of the problem AND definition of desired outcome. The generic dialogue meeting would follow three major steps aimed at:

a. UNDERSTANDING (recognising) the problem from the perspective of the "problem owner",
b. EMPATHISING with the owner of the problem by going deep into factual needs, approaches and success indicators as well as issues, frustrations, headaches and hassles;
c. DEFINING the need by brainstorming the four possible actions that may help to overcome obstacles:
    i. REDUCE factors considered as the standard.
    ii. ELIMINATE factors considered as the standard
    iii. STRENGHTEN factors considered as the standard
    iv. CREATE new factors or standards

The following assumptions are to be taken into consideration when preparing and performing the meeting:

a) The meeting required one or two facilitators prepared to run the workshop by following the three steps described above. The presentation and templates have been provided to all partners of the BFCC project.
b) The meeting required the participation of representatives of at least three different stakeholders– but crucial was involvement and participation of representatives of business sector. The number of participants would not exceed 16 persons.
c) Different techniques aimed to generate and organise ideas, like mind mapping, facilitated dialogue, brainstorming, clustering and similar were possible providing they would allow to foster same quality of results. It was advised to divide participants into smaller groups (max 5 people) in order to foster active participation and maintain dynamics of the conversation.
d) Equipment necessary to perform the meeting involved one flipchart per group and one flipchart to collect notes about best practices.
e) All materials and sources used during the workshop would be collected – permission to use this materials from owners were to be obtained.

2.3. Stakeholders for the innovation dialogue meetings

It was assumed that participants of the IDM would represent different professional background and experience, thus different views for the same issues in question. Following is the list of categories of participants at the meetings:

a) Doctors – clinicians directly involved in clinical procedures for fracture treatment
b) Physiotherapists
c) Technical staff involved in preparation or realisation of procedures for fracture treatment
d) Nurses assisting in procedures for fracture treatment
e) Patients
f) Innovators representing research and development (R&D) sector
g) Innovators representing business sector

It was also assumed that in order to make the dialogue efficient, a minimum participation in each dialogue event would require presence of representatives of at least three listed categories including business sector.

2.4. The innovation dialogue reports (IDR)

Innovation dialogue reports (IDR) were prepared by following basic guidelines, but not exactly the same processes. The focus was to maintain the same structure and standard of the output with the view for securing easy comprehension, comparison and evaluation of identified needs, challenges as well as best practices and potentials. To that end, the IDR abstracts from the method (process) applied to identify a challenge. The structure of the IDM proposed to the project partners aimed to exemplify one of many possible approaches.

The main output of the innovation dialogues are structured reports including the information stipulated in the following table:

#	Table of content	Comment
a)	Title of the opportunity / challenge	Each identified opportunity need to be named by an individual title e.g.
b)	Short description of the opportunity / challenge (one sentence)	Abstraction of the need or opportunity to be attached to the title for example when published in website.
c)	Background	Short and concise description of the background with indication of the key problem which needs to be addressed and solved
d)	Best practices	Description of the best practices which are actually preformed in order to solve the problem.
e)	The need / opportunity	Short and concise description of the need / opportunity addressing concrete performance areas: • What to REDUCE • What to ELIMINATE • What to STRENGHTEN • What to CREATE
f)	Source documents (participants, notes, mind maps, photos etc.)	Copies of notes, graphics, presentations, photos and other materials used to come up with the challenge – this material may become resources for the next steps of the process.
g)	Id of the event (place, date)	Identification of the event – may be useful to compare outcomes from different types of events.
h)	Contact to the lead person	Provide the contact data to the person which may be most helpful in case more information regarding the specific need is required.
i)	Sources	Provide links to sources where additional background information can be obtained.

2.5. Ownership and durability

Result of the workshops have no proprietary value - they represent a problem or an opportunity but not the solution, therefore can be freely shared in and outside the project partnership. The durability of each opportunity cannot be defined - it is rather assumed that each opportunity will eventually discontinue in a natural way following development of new processes and methods or application of direct solutions.

2.6. Conclusion

All the detailed assumptions regarding preparation and execution of IDMs have been included in the quality specifications defined at the beginning of the project. It was assumed that all the IDM performed in participating hospitals in the scope of the project would be pilot, and one of the results would be conclusions regarding the process itself.

3. INNOVATION DIALOGUE

3.1. Partners and events

Partner of GoA 4.2	IDM I	IDM II
Sahlgrenska University Hospital (SE)	Mölndal Hospital; March 9, 2018	Sahlgrenska University Hospital, Mölndal; November 23, 2018
University Medical Center Schleswig-Holstein (DE)	The Newport, Willy-Brandt-Allee 31, 23554 Lübeck; May 31, 2018	The Newport, Willy-Brandt-Allee 31, 23554 Lübeck; June1, 2018
Lithuanian University of Health Sciences (LT)	Lithuanian university of health sciences; June 26, 2018	Lithuanian university of health sciences; October 2, 2018
University Hospital Krakow (PL)	University Hospital Krakow; April 24, 2017	University Hospital Krakow
University of Tartu (EE)	Tartu University Hospital, Department of Traumatology and Orthopaedics; April 13, 2018	Tartu University Hospital, Department of Traumatology and Orthopaedics; August 21, 2018

3.2. Innovation dialogue reports

3.2.1. University Hospital Krakow - Poland

Innovation dialogue 1	
A.	*The need / opportunity (challenge)*
Instrumentation for removal of broken implants	
B.	*Short description of the opportunity (one sentence)*
Surgeons need to be equipped with the set of tools, and instruments of universal nature that would help them remove the parts of the broken implants or fixing elements of different origins that accidentally stuck in the bone.	
C.	*The background – description of the problem*
During a surgical procedure to set a fracture, the bone fragments are first repositioned (reduced) into their normal alignment. They are held together with special implants, such as ***plates***, ***screws***, ***nails*** and ***wires***. Internal fixation allows shorter hospital stays, enables patients to return to function earlier, and reduces the incidence of non-union (improper healing) and malunion (healing in improper position) of broken bones. The implants used for internal fixation are made from stainless steel and titanium, which are durable and strong. There are many types of implants and joints, and no standards as it regards methods and tool of implants removal. **The major surgical problem:** Inability to remove the implant stuck in the bone Difficulty removing an implant can occur if the implant is difficult to locate, if the implant breaks, or in some cases, if it is simply stuck. A repeat fracture happens accidentally when patient is overconfident due to the fact he does not fill a pain anymore. In most cases metal implants can be removed, sometimes causing unnecessary damage to normal bone and soft-tissue. In rare circumstances, the effort to remove an implant may be abandoned and the implant left behind. It is also always a risk that seemingly simple, straight-forward surgical procedure may become more complicated. For that reason, surgeons always should be wary of a hardware removal surgery, as these procedures can become more challenging than anticipated. There are also cases where hardware removal becomes impossible – most often related to a broken metal implant inside the body. When facing the major surgical problem surgeons **most often improvise by combining available tools, instruments, methods and approaches developed ad hoc to address the problem**.	

D.	*Description of the need / opportunity (challenge)*

This is the need for a **design the ready-made set of universal instruments that would be handy in case of necessity of removal of metal implant stuck in the bone**. Instruments need to be designed with the knowledge of diverse types of implants and internal fixations, as well as need to base on idiosyncratic experience of clinicians.
While it is impossible to foresee all the possible complications, it is assumed that well designed set will be supportive in majority of cases and will especially: **speed the procedure, lower damage of soft tissues, lower the risk of other complications** caused by improvisation.

- REDUCE – the necessity to improvise with instruments that are not purposefully designed to remove the implant stuck in the bone
- ELIMINATE – randomness in completing the instrumentation for complicated procedure
- STRENGHTEN – capacity to address the problem correctly
- CREATE – standards for development of implants and supporting instrumentation that makes dealing with complications less problematic

E.	*Supplement: source documents from the workshop (participants, notes, mind maps, photos etc.)*

Participants from the following organisations attended the event:

1. Centrum Urazowe Medycyny Ratunkowej i Katastrof w Szpitalu Uniwersyteckim w Krakowie (CUMRIK), Rehabilitacja
2. CUMRIK
3. CUMRIK
4. STRYKER
5. University Hospital Krakow
6. Johnson&Johnson
7. SUH Medical Devices Dept.
8. SUH DKRP
9. CUMRIK
10. SUH
11. LifeScience Krakow Klaster (facilitator)
12. LifeScience Krakow Klaster (facilitator)

Please note that due to GDPR no person related data are listed.
An event summary is available at the BFCC's project website.

F.	*Id of the event (place, date)*

BFCC Innovation Dialogue Event held in University Hospital Krakow, 24th April 2018

G.	*Contact to the lead person*

Jarosław Brudnicki, CUMRIK

H.	*Sources (other):*

Busam ML, *et al.* "Hardware removal: indications and expectations" J Am Acad Orthop Surg. 2006 Feb;14(2):113-20.

3.2.2. Sahlgrenska University Hospital - Sweden

Innovation dialogue 1	
A.	*The need / opportunity (challenge)*
Opportunity 1 Empowering patients! Opportunity 2 Fracture treatments to go!	
B.	*Short description of the opportunity (one sentence)*
Opportunity 1 What if no patient has unanswered questions after checking out from a hospital? Opportunity 2 What if you could be prepared when performing fracture treatment?	
C.	*The background – description of the problem*
Opportunity 1 Patients are often stressed and still shocked when checking out of the hospital. It is difficult to ensure that the information given is customized and understood by the patient in the situation. Opportunity 2 Resource shortage and high staff turnover make it hard for orthopaedic doctors to free time for skills development and quality assurance. This leads to concern, uncertainty and stress before surgery and increases the risk of medical errors.	
D	*Description of the best practices which are actually preformed in order to solve the problem*
Opportunity 1 No best practice processes are available. Opportunity 2 No best practice processes are available.	
E	*Description of the need / opportunity (challenge)*
Opportunity 1 Correct information to the right patient/care provider at the right time taking into account individual needs when checking out inpatient from the hospital. Opportunity 2 To ensure competence about treatment methods and tools when performing fracture treatment.	

F.	*Supplement: source documents from the workshop (participants, notes, mind maps, photos etc.)*
Participants from the following organisations attended the event: 1. Sahlgrenska University Hospital 2. Sahlgrenska University Hospital 3. Sahlgrenska University Hospital 4. Sahlgrenska University Hospital 5. Sahlgrenska University Hospital 6. Sahlgrenska University Hospital 7. Stryker AB 8. Swematec Innovation AB 9. Bonesupport AB 10. Smith & Nephew 11. Patient from Sahlgrenska University Hospital 12. Patient from Sahlgrenska University Hospital 13. Sahlgrenska University Hospital (facilitator) 14. Sahlgrenska University Hospital (facilitator) Please note that due to GDPR no person related data are listed. An event summary is available at the BFCC's project website.	
G.	*Id of the event (place, date)*
BFCC Innovation Dialogue Event held in Mölndal hospital, 9th March 2018	
H.	*Contact to the lead person*
Anders Jönsson, Sahlgrenska University Hospital	
I.	*Sources (other):*
-	

PHOTO: Adobe Stock

Innovation dialogue 2

A.	*The need / opportunity (challenge)*

Development of a common standard for surgical simulators

B.	*Short description of the opportunity (one sentence)*

Product specific and manufacturer specific simulations training modules would work on different simulators

C.	*The background – description of the problem*

It is well known that surgical training in simulators increases the quality of outcome of performed surgical procedures in real life. Surgical skill training in simulators has been a reality since more than 20 years. The technology is known but not widely applied.
Simulating surgical procedures mimicking the view from screens of image intensifiers during parts of surgical fracture repair using specific implants have been available at least for a decade. We are now in the era of virtual reality (VR) training simulators when a complete surgical intervention could be simulated. To our knowledge development of such VR applied simulators are in progress by several implant manufacturer. These training devices will be product specific and of course connected with the manufactures specific implants. When these new VR based simulator are been more general launched each hospital would need a multiple amount of simulation devices, one from each manufacturer. In turn, this increases the hospital costs, either directly when it is purchased or indirectly when the simulator cost is wrapped in the implants costs.
Today we are not aware of any simulator that simulates a patient specific fracture based on real image data from CT-scans or MRI-scans. Having a worldwide standard for surgical simulators would increase the evolution of such devises and lead to more training and better outcome for patients

D	*Description of the best practices which are actually preformed in order to solve the problem*

Today only limited time is spent on surgical training outside the real surgical operating rooms. Training is performed during surgery

E	*Description of the need / opportunity (challenge)*

Surgical training simulators are commercially available since roughly two decades and parallel to the rapid development of computer and software technologies also computer based simulators have advanced in user reality. Unfortunately, the commercially available simulators for fracture repair on the market are not based on an agreed standard. Implant manufacturers, simulator developers, software developers and other should agree on a common standard in order to make the technology more easily available and in turn providing more simulator training leading to better patient outcome. Having common standard the product specific software could be used on simulators from different manufacturers.

- REDUCE – the thresholds for acquiring surgical training simulators
- ELIMINATE – risk of low quality outcome after surgical fracture repair
- STRENGHTEN – the surgical outcome of fracture patients
- CREATE – a standard for surgical training simulators

F.	*Supplement: source documents from the workshop (participants, notes, mind maps, photos etc.)*

Participants from the following organisations attended the event:

1. Arthrex
2. Bonesupport
3. Anatomica
4. Stryker
5. Smith&Nephew
6. Sahlgrenska University Hospital
7. Sahlgrenska University Hospital
8. Sahlgrenska University Hospital
9. Sahlgrenska University Hospital
10. Sahlgrenska University Hospital
11. Sahlgrenska University Hospital
12. Sahlgrenska University Hospital (facilitator)

Please note that due to GDPR no person related data are listed.

G.	*Id of the event (place, date)*

BFCC Innovation Dialogue II Event held at Sahlgrenska University Hospital, Mölndal, 23rd November 2018

H.	*Contact to the lead person*

Anders Jönsson, Sahlgrenska University Hospital

I.	*Sources (other):*

For review see.

Olasky J, Sankaranarayanan G, Seymour NE, Magee JH, Enquobahrie A, Lin MC, Aggarwal R, Brunt LM, Schwaitzberg SD, Cao CG, De S, Jones DB. Identifying Opportunities for Virtual Reality Simulation in Surgical Education: A Review of the Proceedings from the Innovation, Design, and Emerging Alliances in Surgery (IDEAS) Conference: VR Surgery. Surg Innov. 2015 Oct;22(5):514-21.

Stefanidis D, Sevdalis N, Paige J, Zevin B, Aggarwal R, Grantcharov T, Jones DB; Association for Surgical Education Simulation Committee. Simulation in surgery: what's needed next? Ann Surg. 2015 May;261(5):846-53.

Zeng C, Xing W, Wu Z, Huang H, Huang W. A combination of three-dimensional printing and computer-assisted virtual surgical procedure for preoperative planning of acetabular fracture reduction. Injury. 2016 Oct;47(10):2223-2227.

Girod S, Schvartzman SC, Gaudilliere D, Salisbury K, Silva R. Haptic feedback improves surgeons' user experience and fracture reduction in facial trauma simulation. J Rehabil Res Dev. 2016;53(5):561-570.

3.2.3. University Medical Center Schleswig-Holstein – Germany

Innovation dialogue 1	
A.	*The need / opportunity (challenge)*
Medical Device Regulation (MDR) Post-Market Clinical Follow-up (PMCF) – are joint strategies of clinics and manufacturers necessary? An elaboration of problem areas.	
B.	*Short description of the opportunity (one sentence)*
Definition of problem zones and possible solutions for the planning and implementation of post-marketing clinical follow-ups in the hospital environment.	
C.	*The background – description of the problem*
Translation from website http://www.clinfo.eu/klinische-nachbeobachtung/ (Author: Dr. Andrea Röthler, Head of Project Management, Manager Regulatory Affairs Medical Devices @ GKM Gesellschaft für Therapieforschung) It has been official since 25 May 2017. The new EU Medical Device Regulation (MDR) has entered into force and must be applied from May 26, 2020 after a three-year transitional period. This transition period of 3 years seems to be quite long at first glance, but in view of the extensive new requirements for e.g. the clinical evaluation of medical devices or the demand for continuous clinical follow-up after placing on the market, it is quite tight. This makes it all the more important to familiarise oneself with the new features of MDR and to take them into account now for the first marketing or the post-marketing phase. For many products, clinical evaluation has so far been based purely on the equivalence principle; clinical data from literature and clinical data from clinical trials with one's own product are completely lacking. Against this background, the demand in MDR for continuous clinical follow-up of the products after they have been placed on the market is only understandable. Finally, problems or new risks often only occur after the products have already been placed on the market and are used over a longer period of time or in a larger population of users or patients. In order to continuously record such risks in use and thus ensure effective protection of users or patients even after placing on the market, the post-marketing monitoring of medical devices and their interaction with clinical evaluation in MDR has been newly regulated. Post-Market Clinical Follow-up (PMCF) will become an obligatory part of Post-Market Surveillance (PMS). As a result, manufacturers now have to deal with the question of how to clinically pursue their products and how to proactively collect and evaluate clinical data in the daily routine of their own product as part of a clinical trial or post-marketing surveillance before placing them on the market for the first time. When preparing the PMCF plan, the greatest challenge for the manufacturer will probably be to design the clinical follow-up studies (so-called PMCF studies) in such a way that they are tailored to the type of product or product group. The aim of these PMCF studies is ultimately to test whether an intervention in normal care is effective for a specific population of patients or users. For this reason, it is important that these types of studies also reflect routine care well and that the study design fits the product accordingly.	
D	*Description of the best practices which are actually preformed in order to solve the problem*
There is currently no solution to the problem. Pharmaceutical manufacturers need to get together, exchange ideas, develop joint strategies and involve the doctors in the hospitals in finding solutions.	

E	*Description of the need / opportunity (challenge)*

Industry is facing a great challenge, which the new EU Medical Devices Regulation brings with it for the PMCF and there is great uncertainty. The problems listed below were identified as the 10 most important by the participants.

1. How much data is enough?
2. Do the clinics have sufficient resources at all?
3. The knowledge of clinics about post market studies?
4. How is the cooperation between companies and hospitals?
5. Data quality?
6. Language barrier: clinical scientific studies and regulatory clinical trials?
7. Planning and execution of extensive post-market investigations?
8. Motivation of doctors?
9. Adequate remuneration of doctors?
10. Problems of MDR, specifically the proportion of PMCF?

F.	*Supplement: source documents from the workshop (participants, notes, mind maps, photos etc.)*

Participants:

Technical Staff involved in preparation or realisation of procedures for fracture treatment and innovators, representing the R&D and Business Sector (Signature List)
Please note that due to GDPR no person related data are listed.

An event summary is available at the BFCC's project website.

G.	*Id of the event (place, date)*

ID: BFCC Innovation Dialogue Event – the MDR Breakfast Club
Place: The Newport, Willy-Brandt-Allee 31, 23554 Lübeck
Date: 31.05.2018

H.	*Contact to the lead person*

Prof. Dr. Arndt-Peter Schulz, University Medical Center Schleswig-Holstein

I.	*Sources (other):*

1. https://www.bvmed.de/de/bvmed/presse/pressemeldungen/eu-medizinprodukteverordnung-mdr-im-eu-amtsblatt-veroeffentlicht-inkrafttreten-am-25.-mai-2017 : EU Medizinprodukte-Verordnung (MDR) im EU-Amtsblatt veröffentlicht – Inkrafttreten am 25. Mai 2017

2. http://www.clinfo.eu/klinische-nachbeobachtung/ : Verpflichtung zur klinischen Nachbeobachtung (PMCF) von Medizinprodukten

3. http://www.clinfo.eu/klinische-bewertung-mdr/ : Die klinische Bewertung nach der neuen MDR – de facto Pflicht zur klinischen Prüfung

Innovation dialogue 2

A.	*The need / opportunity (challenge)*

Opportunity 1
Empowering physiotherapists!

Opportunity 2
No waste of time! Focus on what is necessary for hospital physician

B.	*Short description of the opportunity (one sentence)*

Opportunity 1
What if no physiotherapists would worry about data entering, handling technology and programs?

Opportunity 2
What if doctors could concentrate on the essentials of their work - does data collection belong to it?

C.	*The background – description of the problem*

Opportunity 1
Physiotherapists like to work with people and less with computers and computer programs because they do not feel safe in this area.

Opportunity 2
Doctors have little time to deal with the collection of data in addition to their actual work. Unless this recording could be integrated into the normal workflow.

D	*Description of the best practices which are actually preformed in order to solve the problem*

Opportunity 1
No best practice processes are available.

Opportunity 2
No best practice processes are available.

E	*Description of the need / opportunity (challenge)*

Opportunity 1
Physiotherapists should lose their shyness about computer programs, because entering data using the programs could lead to an improvement in data quality and thus in the reports that are generated from these data, from which in turn treatment methods that serve the well-being of patients can be derived.

What to REDUCE?
- The uncertainty of physiotherapists with regard to computer programs
- The fear of too much extra work when additional data is collected

What to ELIMINATE?
- Unnecessary extra work

What to STRENGTHEN?
- Computer skills, program knowledge
- Physiotherapists must be taught how important their role in the fracture register is.
- Knowledge of new treatment methods derived from the data entered

What to CREATE?
- Creation of a solid knowledge base for physiotherapists
- Development of special training programs
- Introduction of super-users who pass on their knowledge to others
- Regular exchange of experience among the physiotherapists
- Manual for data acquisition and report requests

E	Description of the need / opportunity (challenge)

Opportunity 2

Doctors must be encouraged to recognize how important it is to have data on fractures (treatment) in registers, because this is the only way to create a sufficiently large database for evaluations. The question is whether it is absolutely necessary for them to enter this data themselves on the computer or whether there are reasonable ways in which the necessary information could be passed on to other people who would then enter it in the system.

What to REDUCE?
- The doctors' feeling of wasting time entering data unnecessarily

What to ELIMINATE?
- Computer programs that are too slow, so that too much time with waiting is lost during data entering

What to STRENGTHEN?
- Doctors need to be strengthened so that their cooperation is extremely valuable and by no means for nothing

What to CREATE?
- Computer programs that allow the most important information about fractures and treatment methods to be entered quickly and user friendly
- Processes and programs that ensure that information can also be subsequently recorded in the system by third parties
- In order to make the data collected comparable with that of other hospitals, the use of free texts should be avoided as far as possible and uniform standards for the evaluation of various criteria (severity etc.) in the form of selection boxes or drop-down fields should be integrated into the mask for data entry.

F.	Supplement: source documents from the workshop (participants, notes, mind maps, photos etc.)

Participants:
Doctors, nurses, physiotherapists and hospital engineers working in a hospital with a fracture treatment department (Signature List)

Please note that due to GDPR no person related data are listed.
An event summary is available at the BFCC's project website.

G.	Id of the event (place, date)

ID: BFCC Innovation Dialogue Event II
Place: The Newport, Willy-Brandt-Allee 31, 23554 Lübeck
Date: 01.06.2019

H.	Contact to the lead person

Prof. Dr. Arndt-Peter Schulz, University Medical Center Schleswig-Holstein

I.	Sources (other):

-

3.2.4. Lithuanian University of Health Science - Lithuania

Innovation dialogue 1	
A.	*The need / opportunity (challenge)*
• Infection prevention • Quality criteria of medical implants	
B.	*Short description of the opportunity (one sentence)*
• Infection prevention. The goals of fracture management are prevention of infection, fracture healing, and restoration of function. • Quality criteria of medical implants. The requirements of medical devices used in patients are increasing, however, it is unclear what clinical results are suggested as good.	
C.	*The background – description of the problem*
Infection prevention. Implant-related infections after fractures are important to understand as it requires repeated surgeries, hospitalizations, secondary complications, sometimes amputations, chronic morbidity, and mortality related to the systemic antibiotic treatment and immobilization. Infection prevention principles vary between closed and open fractures. For open fractures, the principles are following: careful patient and injury evaluation, early administration of systemic antibiotics supplemented by local delivery of antibiotics in severe injuries, thorough surgical debridement, wound management with soft tissue coverage if needed, and stable fracture fixation. Also, preoperative, perioperative, intraoperative, and postoperative strategies/measures to decrease infection rate are discussed. These measures suggest that infection prevention requires a multidisciplinary approach with various strategies. However, some infection prevention strategies are supported by the literature whereas others remain unproven. Quality criteria of medical implants. The annual number of fractures in the EU will rise up to 28% from 3.5 million in 2010 to 4.5 million in 2025 (1). As the result, the use of surgically implanted devices is also increasing. Surgical fracture treatment with various types of implants is usually successful. However, like every medical intervention it is associated with various complications. Any complications result in the overall increase of total healthcare costs and length of stay. Thus, there is a special interest to decrease complications and requirements for medical devices are increasing. Safe implants could be understood in terms of sterile, biomechanically durable and demonstrating good clinical results. However, there is a lack of knowledge what the quality criteria which define good clinical outcome are. There are clinical trials or register studies which demonstrates revision and/or reoperation rates. The increased demand for international performance standards in implant use emphasizes the need for a standardized benchmarking system.	

D	*Description of the best practices which are actually preformed in order to solve the problem*
Infection prevention. There are numerous reports/guidelines in infection prevention/treatment strategies, however, with a huge variability between continents, countries or even hospitals. This may be affected by the lack of randomized controlled trials in infection field, as it is may be bioethically difficult to approve them. This makes large cohort studies crucial. Countries with implemented well defined infection prevention/treatment algorithms may have significantly lower infection rates as compared to countries which have no algorithms established on national level. This can be evaluated in international collaboration projects. Quality criteria of medical implants. When defining the quality criteria, it is important to ensure the development of a transparent, evidence-based system that is acceptable to concerned parties and relevant stakeholders worldwide. In some countries there are institutions evaluating the quality of joint arthroplasty implants. In UK ODEP (Orthopaedic Data Evaluation Panel) was set up by National Health Purchasing and Supply Agency (PASA, subsequently replaced by NHS Supply Chain) as a response to National Institute for Health and Care Excellence (NICE) issuing guidance relating to Total joint replacement. ODEP ratings provide a simple, independently verified assessment as to the performance of an implant, assessed against national clinical best practice guidelines. This enables clinicians to ensure that the implants that they use comply with the guidelines.	
E	*Description of the need / opportunity (challenge)*
Infection prevention. There is a need for international collaboration to perform large cohort studies analysing the infection prevention strategies. • REDUCE – the clinically unproven variables between participating hospitals. • ELIMINATE – identify and discontinue harmful infection prevention measures as early as possible. • STRENGHTEN – unified infection data measures form must be used in order to reinforce the analysis. • CREATE – a platform which enables large international cohort studies. • Quality criteria of medical implants. There is a need to create international performance standards in implant use and benchmarking system. Implant benchmarking may be useful for many stakeholders. Also, when tested implants are used it helps all concerned parties (patient, surgeon, hospital, insurance and government) to choose the device which has been independently assessed as having an acceptable and proven quality of performance. • REDUCE – the incomplete data collection. • ELIMINATE – irrelevant, obscure data collection. • STRENGHTEN – ensure independent, transparent and evidence-based system when registering the outcome. Ensure the completeness and validity of the registry. • CREATE – a platform registering clinical data of primary, revision procedures, complications in fractured patients. Regarding the outcomes to create a benchmarking system.	

F.	*Supplement: source documents from the workshop (participants, notes, mind maps, photos etc.)*

Participants from the following organisations attended the event:

1. Lithuanian University of Health Sciences (Orthopaedic surgeon)
2. Lithuanian University of Health Sciences (Orthopaedic surgeon)
3. Lithuanian University of Health Sciences (OR Nurse)
4. Lithuanian University of Health Sciences (Orthopaedic surgeon, resident)
5. Lithuanian University of Health Sciences (Orthopaedic surgeon)
6. Lithuanian University of Health Sciences (Student)
7. Lithuanian University of Health Sciences (Orthopaedic surgeon)
8. Osteca (Implant dealer)
9. Lithuanian University of Health Sciences (Orthopaedic surgeon, resident)
10. Lithuanian University of Health Sciences (Orthopaedic surgeon, resident)
11. Lithuanian University of Health Sciences (Orthopaedic surgeon, resident)
12. Lithuanian University of Health Sciences (Orthopaedic surgeon)
13. Lithuanian University of Health Sciences (Orthopaedic surgeon)
14. Lithuanian University of Health Sciences (Sport medicine physician)
15. Lithuanian University of Health Sciences (Orthopaedic surgeon, resident)
16. Lithuanian University of Health Sciences (Orthopaedic surgeon)

Please note that due to GDPR no person related data are listed.
An event summary is available at the BFCC's project website.

G.	*Id of the event (place, date)*

BFCC Innovation Dialogue Event I, Lithuania, 26th June 2018.

H.	*Contact to the lead person*

Justinas Stučinskas, Lithuanian University of Health Sciences

I.	*Sources (other):*

Jämsen E, Furnes O, Engesaeter LB, Konttinen YT, Odgaard A, Stefánsdóttir A, Lidgren L. Prevention of deep infection in joint replacement surgery. Acta Orthop. 2010; 81(6):660-6. 2. Zimmerli W, Trampuz A, Ochsner PE. Prosthetic-joint infections. N Engl J Med. 2004; 351(16):1645-54.

Innovation dialogue 2

A.	*The need / opportunity (challenge)*

- Implant alignment in proximal femoral fractures
- Local biofilm treatment

B.	*Short description of the opportunity (one sentence)*

- Implant alignment in proximal femoral fractures. Precise placement of implants is related with greater stabilization and may prevent from loss of fracture reduction.
- Local biofilm treatment. Fighting the biofilm in infected fractures is an important challenge.

C.	*The background – description of the problem*

- Implant alignment in proximal femoral fractures. Hip fractures are the most common fractures in the elderly and have consequences extending into the domains of medicine, rehabilitation, psychiatry, social work and medical economics. Hip fracture patients are related with high morbidity, decrease in quality of life and high mortality ranging from 14 till 58%.
  Proximal femoral fractures in absolute majority of patients are operated. If the fractures are fixed/osteosynthesis performed, the alignment of implants is very important together with anatomical reduction of fragments. Precise placement of implants is related with greater stabilization and may prevent from loss of fracture reduction, thus surgical failure.
  Preparation of screw implantation is usually starting with introduction of guide wire. If it's malaligned the final implantation will be not precise. The guide wire is entered from lateral cortex of the proximal femur and by eye directed to the femoral head under the fluoroscopy control. The entering angle may vary depending on individual patient anatomy or the type of the implant. The placement of initial guide wire could be enhanced if the surgeon could see were the wire will be before the insertion.
- Local biofilm treatment. Implant-related infections after fractures often requires repeated surgeries, hospitalizations, are related with secondary complications, sometimes amputations, chronic morbidity, and mortality related to the systemic antibiotic treatment and immobilization. Infected fractures or pseudoarthrosis requires both fracture fixation and infection treatment. This is compromised as long as the foreign material is present, together with conditions to form a biofilm.

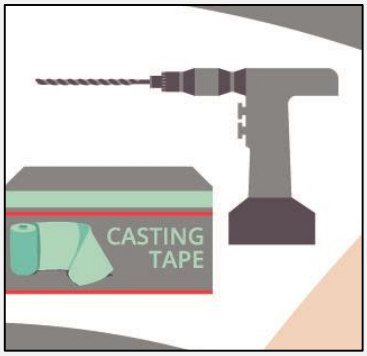
D	*Description of the best practices which are actually preformed in order to solve the problem*

- Implant alignment in proximal femoral fractures. There are numerous reports/guidelines in infection prevention/treatment strategies, however, with a huge variability between continents, countries or even hospitals. This may be affected by the lack of randomized controlled trials in infection field, as it is may be bioethically difficult to approve them. This makes large cohort studies crucial. Countries with implemented well defined infection prevention/treatment algorithms may have significantly lower infection rates as compared to countries which have no algorithms established on national level. This can be evaluated in international collaboration projects.
- Local biofilm treatment. The usual strategy in early stages is a suppression of bone infection and removal of implant as soon as fracture is healed. In complicated cases bone healing could be prolonged and suppression alone could be insufficient, thus require biofilm-active therapy. However, local antibiotics in bone cement can interfere with polymerization process (e.g. rifampin or metronidazol) or which are not thermostable or sensitive to oxidation (e.g. some beta lactams) and cannot be used.

E	*Description of the need / opportunity (challenge)*

Implant alignment in proximal femoral fractures. There is a need to improve an accuracy of implant placement in femoral neck.

- REDUCE – the number of fluoroscopic images/fluoroscopy and operation time.
- ELIMINATE – implant malalignment.
- STRENGHTEN – improve an accuracy of implant placement in femoral neck and prevent from loss of fracture reduction.
- CREATE – a device which could be fastened to any power tool and being parallel to original guide wire but prolonged on the top of the patient like an arm. It could be a cheap alternative as compared to navigation systems.



Local biofilm treatment. Fighting the biofilm locally could enhance the treatment of infected fractures.

- REDUCE – the failure rate of infection treatment.
- ELIMINATE – n.a.
- STRENGHTEN – support systemic antibiotic therapy with biofilm-active therapy.
- CREATE – a local antimicrobial delivery/possible carriers for biofilm-active or supportive therapy.

F.	*Supplement: source documents from the workshop (participants, notes, mind maps, photos etc.)*

Participants from the following organisations attended the event:

1. Lithuanian University of Health Sciences (Orthopaedic surgeon)
2. Lithuanian University of Health Sciences (Orthopaedic surgeon)
3. Lithuanian University of Health Sciences (OR Nurse)
4. Lithuanian University of Health Sciences (Orthopaedic surgeon, resident)
5. Lithuanian University of Health Sciences (Orthopaedic surgeon)
6. Lithuanian University of Health Sciences (Orthopaedic surgeon)
7. Lithuanian University of Health Sciences (Orthopaedic surgeon)
8. Lithuanian University of Health Sciences (Orthopaedic surgeon)
9. Lithuanian University of Health Sciences (Orthopaedic surgeon)
10. Lithuanian University of Health Sciences (Orthopaedic surgeon)
11. Lithuanian University of Health Sciences (Orthopaedic surgeon)
12. Lithuanian University of Health Sciences (Orthopaedic surgeon)
13. Lithuanian University of Health Sciences (Orthopaedic surgeon)
14. Lithuanian University of Health Sciences (Orthopaedic surgeon)
15. Lithuanian University of Health Sciences (Orthopaedic surgeon, resident)

Please note that due to GDPR no person related data are listed.
An event summary is available at the BFCC's project website.

G.	*Id of the event (place, date)*

BFCC Innovation Dialogue Event held in Lithuanian university of health sciences, 2nd October 2018.

H.	*Contact to the lead person*

Justinas Stučinskas, Lithuanian University of Health Sciences

I.	*Sources (other):*

1. Schnell S, Friedman SM, Mendelson DA, Bingham KW, Kates SL. The 1-Year Mortality of Patients Treated in a Hip Fracture Program for Elders. Geriatr Orthop Surg Rehabil. 2010;1(1): 6–14.
2. Brauer CA, Coca-Perraillon M, Cutler DM, Rosen AB. Incidence and mortality of hip fractures in the United States. JAMA. 2009;302(14):1573–9.
3. Roche JJ, Wenn RT, Sahota O, Moran CG. Effect of comorbidities and postoperative complications on mortality after hip fracture in elderly people: prospective observational cohort study. BMJ. 2005;331(7529):1374.
4. Bentler SE, Liu L, Obrizan M, Cook EA, Wright KB, Geweke JF, Chrischilles EA, Pavlik CE, Wallace RB, Ohsfeldt RL, Jones MP, Rosenthal GE, Wolinsky FD. The aftermath of hip fracture: discharge placement, functional status change, and mortality. Am J Epidemiol. 2009;170(10):1290–1299.
5. Haleem S, Lutchman L, Mayahi R, Grice JE, Parker MJ. Mortality following hip fracture: trends and geographical variations over the last 40 years. Injury. 2008;39(10):1157-63.
6. Poenaru DV, Prejbeanu R, Iulian P, Haragus H, Popovici E, Golet I, Vermesan D. Epidemiology of osteoporotic hip fractures in Western Romania. Int Orthop. 2014;38(11):2329-34.
7. Müller MC, Belei P, Pennekamp PH, Kabir K, Wirtz DC, Burger C, Weber O. Three-dimensional computer-assisted navigation for the placement of cannulated hip screws. A pilot study. Int Orthop. 2012 Jul;36(7):1463-9.
8. Jämsen E, Furnes O, Engesaeter LB, Konttinen YT, Odgaard A, Stefánsdóttir A, Lidgren L. Prevention of deep infection in joint replacement surgery. Acta Orthop. 2010; 81(6):660-6.
9. Zimmerli W, Trampuz A, Ochsner PE. Prosthetic-joint infections. N Engl J Med. 2004; 351(16):1645-54.
10. Vinh DC, Embil JM. Device-related infections: a review. J Long Term Eff Med Implants. 2005;15(5):467-88.
11. Peter E Ochsner et al., Swiss Orthopaedics, Swiss Society for Infectious Diseases. Infections of the musculoskeletal system: basic principles, prevention, diagnosis and treatment. Grandvaux : Swiss Orthopaedics, 2014. First English edition.

PHOTO: Adobe Stock

3.2.5. Uniersity of Tartu - Estonia

Innovation dialogue 1

A.	*The need / opportunity (challenge)*
Complications registration - mapping the situation. Disorders in registration of complications.	

B.	*Short description of the opportunity (one sentence)*
The goal is to get all complication registered. In department of traumatology 30% and in department of orthopaedics 15% of the complications are not registered. To find out reasons why some complications are not registered.	

C.	*The background – description of the problem*
All patient complications are not registered. The reasons could be following: 1) It is possible to close patient file without defining complication. 2) Data entering is time consuming 3) Some complications are appearing after patient leave from the hospital 4) Within 30 days rehospitalisation are not counted.	

D	*Description of the best practices which are actually preformed in order to solve the problem*
Best practices – involve IT knowledge in registering the data in electronic patient files 1) You cannot close file before ticking complication field. 2) Simplify the data entry system 3) Quality check by the head of department etc. 4) Electronic system warns in case of readmission	

E	*Description of the need / opportunity (challenge)*
What to REDUCE - reduce time for entering data to the registry • What to ELIMINATE – eliminate unnecessary field in program • What to STRENGHTEN – strengthen accuracy of the data entering • What to CREATE – create valid database/registry of complications, fulfils more the need of orthopaedic patients/ more specialty specific	

F.	*Supplement: source documents from the workshop (participants, notes, mind maps, photos etc.)*
Participants from the following organisations attended the event: 1. Tartu University Hospital 2. Tartu University Hospital 3. Tartu University Hospital 4. Tartu University Hospital 5. Tartu University Hospital 6. Tartu University Hospital 7. Tartu University Hospital 8. Tartu University Hospital 9. University of Tartu 10. University of Tartu Please note that due to GDPR no person related data are listed.	

G.	*Id of the event (place, date)*
Tartu University Hospital, Department of Traumatology and Orthopaedics. Tartu, 13.04.2018.	

H.	*Contact to the lead person*
Professor Aare Märtson, University of Tartu	

I.	Sources (other):
The Tartu University Hospital complication registry is firewall protected and available only for doctors of the hospital.	

Innovation dialogue 2

A.	The need / opportunity (challenge)
Simplification of transfer the local database data to BFCC complication registry.	
B.	Short description of the opportunity (one sentence)
Tartu University Hospital obtains complication registry. To compare complications and treatment procedures and complication profile is important to harmonise data with other Hospitals. BFCC complication registry is good opportunity for these matters. For that we should find the best practices to use existing databases and the ways to transfer data from electronic patient files to the BFCC database. How to improve existing electronic patient files filling for better transfer data from one database to other and how to improve the process of filling the data into the registry to maintain transferability.	
C.	The background – description of the problem
Problems occurred: 1) Databases are not compatible, all data may not be accommodated 2) Some data are not retrievable and some data is not accessible from complication registry 3) not all the complications are registered in all databases on the same basis (there is no internationally accepted system)	
D	Description of the best practices which are actually preformed in order to solve the problem
Training IT personnel in medical needs for better understanding of databases/only special data extraction You need good IT support Try to harmonise database fields	
E	Description of the need / opportunity (challenge)
• What to REDUCE - reduce number of unnecessary fields, • What to ELIMINATE – eliminate unnecessary information • What to STRENGHTEN – involve IT personnel • What to CREATE – create compatible databases	

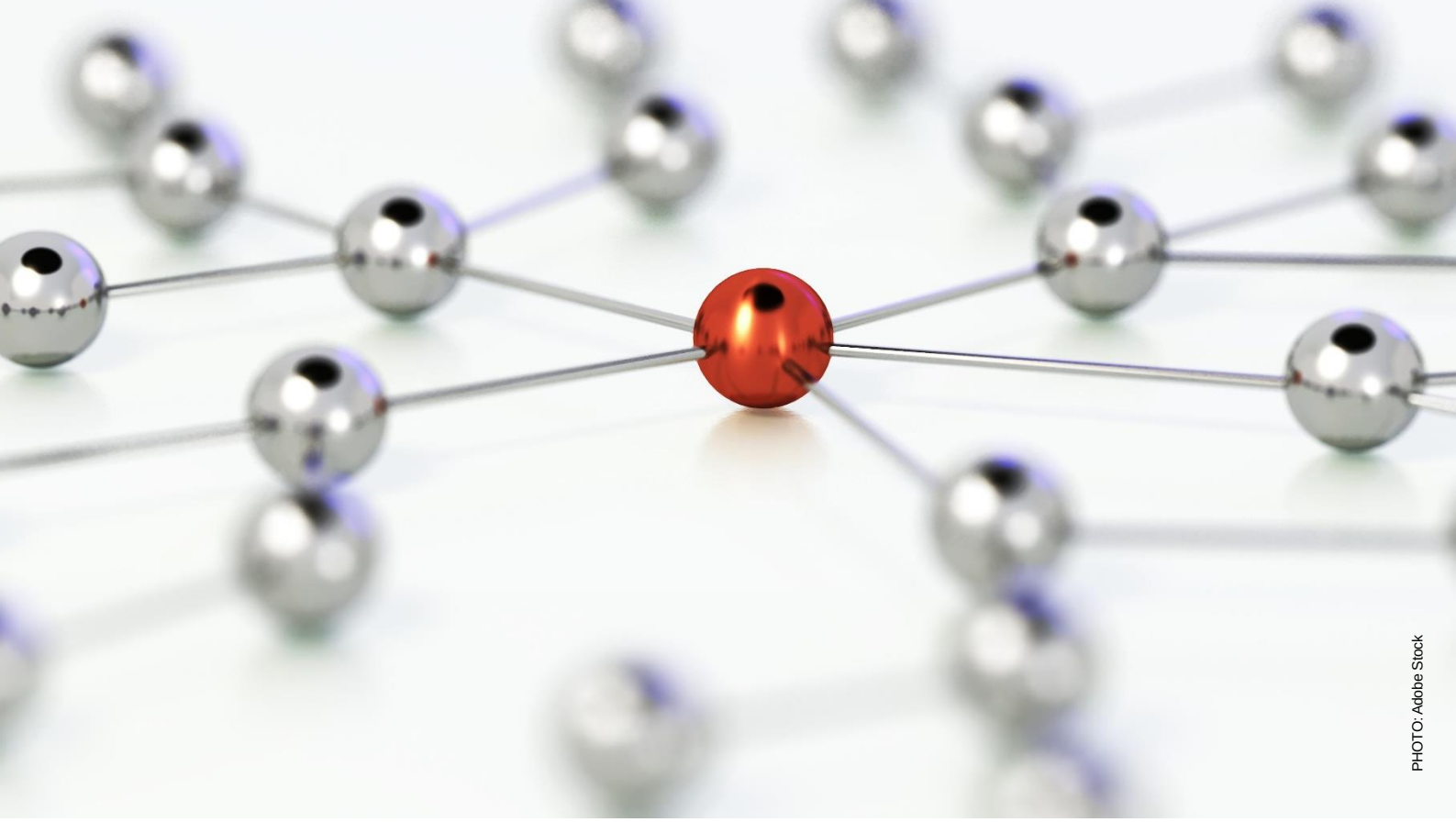


PHOTO: Adobe Stock

F.	*Supplement: source documents from the workshop (participants, notes, mind maps, photos etc.)*
Participants from the following organisations attended the event: 1. Tartu University Hospital 2. Tartu University Hospital 3. Tartu University Hospital 4. Tartu University Hospital 5. Tartu University Hospital 6. Tartu University Hospital 7. Tartu University Hospital 8. Tartu University Hospital 9. University of Tartu Please note that due to GDPR no person related data are listed.	
G.	*Id of the event (place, date)*
Tartu University Hospital, Clinic of Traumatology and Orthopaedics. Tartu, 21.08.2018.	
H.	*Contact to the lead person*
Professor Aare Märtson, University of Tartu	
I.	*Sources (other):*
The Tartu University Hospital complication registry is firewall protected and available only for doctors of the hospital.	

4. RECOMMENDATIONS ON CLINICAL INNOVATION NEEDS AND BEST PRACTICE

Recommendation, possibilities and starting points for future innovation have been collected as the outcomes from stakeholder's meetings and 'innovation dialogues' executed as pilot activities aimed to (a) identify innovation needs and clinical best practice as well as (b) test the approach. The scope of analysis of the innovation needs depends on the type of the problem that needs a solution, i.e. is it technology, process or combination of both.

Recommendation	Type of the problem
a. Improve monitoring and control of healing process in general	process
b. Improve detection of delayed healing process	technology
c. Influence fracture healing to speed up or slow down healing process	process
d. Improve detection of pseudo arthrosis	technology
e. Develop active control of optimal loading of the fracture gap	process
f. Improve measuring of current force during fracture healing	technology
g. Develop intelligent implants	technology
h. Reduce radiation	technology
i. Develop better implants: material which does not dissolve; better surfaces; is hydroxyapatite non-plus-ultra?	technology
j. Improve tele medical data transfer which would allow a faster reaction to unforeseen incidents	process
k. Develop simulation procedures which allow patient-specific prognosis of cure through consolidated data basis	process, technology
l. Improve treatment of fractured symphysis caused by torn out plates, nails and screws.	technology

5. CONCLUSIONS

a) The **quality of outcomes** from innovation dialogues performed in hospital is random and depend on several factors including the structure of participants, the starting point of the discussion and the process of the dialogue, time available to define and discuss the problem.

b) There is not only one method recommended – a **variety of methods** may bring better results, providing they are developed and implemented with the clear objective to identify the problem and define the challenge.

c) A **management process** has to be established in the hospital and aimed to identify and define problems which can be later submitted as challenge to the community of innovators. If this type of action in the hospital is occasional the results will be rather random. Established process would be improved with each round of execution and would feedback to the stakeholders as practical and effective tool to improve their performance.

d) The process involving different stakeholders proved to be very effective in identifying the areas of unsolved problems providing all participants are active and play in the dialogue equal roles. Especially valuable is participation and an input from nurses and other staff which have best possible **access to patients** and which can directly collect feedbacks regarding some services and performances.

e) Participation of business sector provides valuable insight into the problems in hand itself as well as into the issues related to the **process of development and implementation of innovative ideas**. It has been reported that the input from a business perspective helped to improve the report in order to make it fit to business standards.

PHOTO: Adobe Stock